

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA)
EX REL. [RELATORS])
(CONSOLIDATED))
Plaintiffs,)
-against-)
SMITHKLINE BEECHAM, INC. and)
GLAXOSMITHKLINE PLC d/b/a)
GLAXOSMITHKLINE)
Defendant)

C.A. No. 11-10398, 03-10641
11-10741, 11-10921-RWZ

**FILED IN CAMERA AND UNDER
SEAL PURSUANT TO
31 U.S.C. § 3730**

STATEMENT CONCERNING RESOLUTION PROCESS

The United States hereby submits this response to the Court's inquiry as to the steps necessary to finalize the proposed resolution between the parties. The proposed resolution of these consolidated matters is part of a larger resolution of civil and criminal liability of GlaxoSmithKline ("GSK") for this conduct and other conduct. This memorandum will first briefly describe the pieces of the overall resolution and then the steps necessary to complete the process.

The proposed resolution includes the following:

- (1) Civil resolution of \$1,042,600,000 for the federal and state Medicaid claims in the four qui tam pending and consolidated before this Court *United States, et al., ex rel. []*, *et al. v. GlaxoSmithKline* (C.A. No. 11-10398); *United States, et al., ex rel. [] v. GlaxoSmithKline, et al.* (C.A. No. 03-10641); *United States ex. rel [] v. GlaxoSmithKline PLC* (C.A. No. 11-10741) and *United States ex. rel[] v. GlaxoSmithKline PLC, et al.* (C.A. No. 11-10921) for allegations of off-label promotion of Wellbutrin, Paxil, Advair, Lamictal, Zofran and kickbacks with respect to these and other drugs; and a related criminal plea, with a fine and forfeiture;

- (2) A civil resolution and companion criminal plea regarding a drug that is not part of the qui tams pending before the Court;
- (3) A civil resolution of False Claims Act allegations relating to pricing conduct that is not part of the qui tams pending before the Court.

The proposed civil resolutions will also include interest on the civil amounts above at the rate of 1.625% from December 1 until date of payment:

STEPS TO RESOLUTION:

The following is a summary of the necessary steps to finalize the proposed resolution, including obtaining all necessary approvals. This is a summary of the key steps that the undersigned currently anticipates civil, criminal and administrative. However, in many complex settlements of the type here, new issues have arisen as the process progressed that were not anticipated at the beginning of the process.

I. CIVIL RESOLUTIONS:

The steps to be taken for each of the three civil resolutions (separate) include:

- (1) Civil Department of Justice ("DOJ") Approval: Authority must be given to enter into the proposed settlement from the U.S. Attorney in Boston and from the Assistant Attorney General for the Civil Division ("AAG"). A memorandum seeking this authority has already been sent to Washington to start making its way up the approval chain.
- (2) Federal Civil Agreement: The Civil Settlement Agreement must be:
 - (a) negotiated with GSK;
 - (b) approved by the Department of Health and Human Services ("HHS") and the other agencies signing - Veteran's Administration, Office of Personnel Management and Department of Defense, where included;
 - (c) approved by the Director of the Commercial Litigation Branch at DOJ.
- (3) State Civil Agreement. GSK and the State Medicaid negotiating team must also work out a civil settlement agreement, which is usually modeled after the federal civil agreement.

- (4) Relators' Agreements: In order to settle the qui tams, the Relators must either agree or the Court must find that the settlement is fair, adequate and reasonable. Thus far, the four Relators in the first two cases have agreed that the settlement is fair, adequate and reasonable, but we are still waiting to hear back from two other Relators.
- (5) The United States and the Relators either must either agree on an appropriate Relators' share or the dispute must be resolved by the Court (which can happen after the settlement with GSK). This may also require a separate settlement agreement with Relators.
- (6) Relators' shares and agreements must also be approved by the AAG.
- (7) Relators may also have additional claims against GSK for attorney's fees or employment related claims which they may seek to resolve at this time but need not resolve at this time.
- (8) Shortly before the date of the proposed final settlement, if it has not occurred before, the United States will seek authority to unseal the case in order that the Complaints and settlement papers can be made part of the public record.

Payment of the civil resolution amount in this matter will be predicated on acceptance of the proposed criminal resolutions and thus will not occur until the pleas are accepted and the sentences imposed. After those payments are made, stipulations of dismissal at least of the claims on behalf of the governments should be filed.

We believe that all the federal civil agreements will be prepared by February 1, 2012. It often takes about another 60 days for the states to get state decisions as to whether they will join the settlements and given the complexity of this settlement, that is not likely to be less here. Thus, we would hope that the civil agreements would be ready to be signed by April 2, 2012.

II. CRIMINAL RESOLUTIONS

Criminal Plea and Information: These have already been drafted and drafts sent to GSK. They must be agreed upon, and then approved at appropriate levels in the Department of Justice. We are hopeful that this process can be completed by March 2, 2012.

III. ADMINISTRATIVE/COMPLIANCE ISSUES

HHS Office of Inspector General ("HHS OIG") must determine what the appropriate administrative remedy is for these matters. Assuming the parties can reach an agreement on the appropriate administrative remedies, a Corporate Integrity Agreement will have to be discussed, drafted and negotiated with HHS OIG. A meeting occurred on December 14, 2011 as part of the

process of explaining GSK's current compliance procedures and discussing potential changes and a further meeting is scheduled for January 12 and/or 13th. In addition, there may be non-monetary terms negotiated as part of the DOJ resolution.

The resolution of administrative/compliance issues is usually the most substantive and time-consuming part of the resolution process once the other key terms of the deal are determined. We believe that it is not realistic to expect that this could appropriately be accomplished before May 1, 2012.

IV. GSK CORPORATE REQUIREMENTS

GSK may require some short period of time to obtain final approvals and/or corporate authority from the Board of Directors once all documents are finalized. GSK does not anticipate requiring more than an additional week or two to obtain necessary approvals and/or corporate authority.

Dated: December 20, 2011
Boston, Massachusetts

Respectfully submitted,

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